IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Genoveffa Franchini et al. Applicant:

Examiner:

Jeffrey S. Parkin

Serial No.:

10/048,072

Group Art Unit:

1648

Filed:

January 25, 2002

Docket:

1662.018US1

Title:

Immunotherapy In HIV Infected Persons Using Vaccines After Multi-Drug

Treatment

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 et. seq., the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(c)(2), please charge Deposit Account No. 19-0743 in the amount of \$180.00 as set forth in 37 C.F.R. §1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 19-0743.

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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

Respectfully submitted,

GENOVEFFA FRANCHINI ET AL.

By their Representatives, SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. Box 2938 Minneapolis, MN 55402 (516) 795-6820

Date May 16, 2005 By \_\_\_\_\_

Robin A. Chadwick Reg. No. 36,477

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this \_\_16TH \_\_ day of May, 2005.

Alexandria, VA 22515-1450, on this <u>10111</u> day of may, 2003.

PATRICIA A. HULTMAN

Name

Signature

Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 10/048,072 STATEMENT BY APPLICANT January 25, 2002 **Filing Date** (Use as many sheets as necessary) Franchini, Genoveffa **First Named Inventor Group Art Unit** 1648 MAY 1 9 2005 **Examiner Name** Parkin, Jeffrey \* Dans Attorney Docket No: 1662.018US1 Sheet 1 of 2

FOREIGN PATENT DOCUMENTS								
.Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T <sup>2</sup>				
	WO-98/08539A1	03/05/1998	Rutter, Willian J., et al.					

	ОТН	ER DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		"Results from EV01 HIV Vaccine trial, London and Lausanne, June 7th, 2004", (2004),1 Page	
		ADIS INTERNATIONAL LTD., "HIV gp120 vaccine - VaxGen: AIDSVAX,	
		AIDSVAX B/B, AIDSVAX B/E, HIV gp120 vaccine - Genentech, HIV gp120 vaccine AIDSVAX - VaxGen, HIV vaccine AIDSVAX - VaxGen.", <u>Drugs R D., 4(4).</u>	
		(2003),249-53  AMARA, R R., "Studies on the cross-clade and cross-species conservation of	
		HIV-1 Gag-specific CD8 and CD4 T cell responses elicited by a clade B DNA/MVA vaccine in macaques", Virology, 334 (1), (March 30, 2005),124-33	
		BAYES, M, "Gateways to clinical trials", Methods Find Exp Clin Pharmacol., 26(4), (May 2004),295-318	
		BOLESTA, E, "Clustered epitopes within the Gag-Pol fusion protein DNA vaccine enhance immune responses and protection against challenge with recombinant vaccinia viruses expressing HIV-1 Gag and Pol antigens", Virology, 332(2). (February 20, 2005),467-79	
		FRANCHINI, G, "Poxvirus-based vaccine candidates for HIV: two decades of experience with special emphasis on canarypox vectors", Expert Rev Vaccines, 3(4 Suppl), (August 2004),S75-88	
		FRANCHINI, G, et al., "Sequence of simian immunodeficiency virus and its relationship to the human immunodeficiency viruses", <u>Nature</u> , 328(6130), (August 6-12, 187),539-43	
		HEL, ZDENEK, "Viremia control following antiretroviral treatment and therapeutic immunization during primary SIV251 infection of macaques", Nature Medicine, 6(10), (October 2000),1140-1146	
		JIN, XIA, et al., "Safety and Immunogenicity of ALVAC vCP1452 and Recombinant gp160 in Newly Human Immunodeficiency Virus Type 1-Infected Patients Treated with Prolonged Highly Active Antiretroviral Therapy", Journal of Virology, Vol. 76, No. 5, (2002),2206-2216	
		LEE, D, "Breakthrough infections during phase 1 and 2 prime-boost HIV-1 vaccine trials with canarypox vectors (ALVAC) and booster dose of recombinant gp120 or gp160", <u>J Infect Dis., 190(5)</u> , Epub 2004 Jul 29,(September 1, 2004),903-7	
		MONTEFIORI, D C., "Demographic factors that influence the neutralizing antibody response in recipients of recombinant HIV-1 gp120 vaccines", <u>J Infect Dis.</u> , 190(11), Epub 2004 Oct 28,(December 1, 2004),1962-9	

EXAMINER

**DATE CONSIDERED** 

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Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE 10/048,072 **Application Number** STATEMENT BY APPLICANT (Use as many sheets as necessary ) P E January 25, 2002 Filing Date Franchini, Genoveffa **First Named Inventor** 1648 **Group Art Unit** MAY 1 9 2005 Parkin, Jeffrey **Examiner Name** Attorney Docket No: 1662.018US1 Sheet 2 of 2

	ОТНІ	ER DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		PERRIN, L, "Therapeutic vaccination in primary HIV infection, the Quest trial", Vaccine, 20(15), (May 6, 2002),2004-6	
		SADAGOPAL, S, "Signature for long-term vaccine-mediated control of a Simian and human immunodeficiency virus 89.6P challenge: stable low-breadth and low-frequency T-cell response capable of coproducing gamma interferon and interleukin-2", Journal of Virology, 79(6), (March 2005),3243-53	
-		SINGH, D K., "A noninfectious simian/human immunodeficiency virus DNA vaccine that protects macaques against AIDS", <u>Journal of Virology</u> , 79(6), (March 2005),3419-28	
		SMITH, J M., "DNA/MVA vaccine for HIV type 1: effects of codon-optimization and the expression of aggregates or virus-like particles on the immunogenicity of the DNA prime", AIDS Res Hum Retroviruses, 20(12), (December 2004),1335-47	
		SMITH, J M., "Studies in macaques on cross-clade T cell responses elicited by a DNA/MVA AIDS vaccine, better conservation of CD8 than CD4 T cell responses", AIDS Res Hum Retroviruses, 21(2), (February 2005),140-4	
		THIEBOT, HUGUES, et al., "Impact of bone marrow hematopoiesis failure on T-cell generation during pathogenic simian immunodeficiency virus infection in macaques", Blood, 105(6), (March 15, 2005),2403-2409	